

Application Number 10/767,545  
Amendment responsive to Final Office Action mailed July 30, 2007

### **REMARKS**

This Amendment is responsive to the Final Office Action dated July 30, 2007. This Amendment is submitted with, and constitutes the required submission for, a Request for Continued Examination. Applicant has amended claims 19, 24, 27, 35, 37, 42, 45, 53 and 54, and cancelled claims 1-18. Claims 19-54 will be pending upon entry of this amendment.

#### **Claim Rejection Under 35 U.S.C. § 102(b)**

The Final Office Action rejected claims 19-29, 32-47, 50-54 under 35 U.S.C. § 102(b) as being anticipated by Kroll et al. (US 7,123,961, herein referred to as "Kroll"). Applicant respectfully traverses the rejection to the extent such rejection may be considered applicable to the amended claims. Kroll fails to disclose each and every feature of the claimed invention, as required by 35 U.S.C. § 102(b), and provides no teaching that would have suggested the desirability of modification to include such features.

#### ***Independent claims 19 and 37***

Kroll fails to teach or suggest a computer-readable medium comprising instructions to cause a processor to select a first parameter configuration for a neurostimulator, receive an indication of observed efficacy of the first parameter configuration, select a branch of a decision tree based on the indication of observed efficacy and a position of the first parameter within the decision tree, wherein the decision tree defines a hierarchy of possible parameter configurations; and select a second parameter configuration for the neurostimulator based on the selected branch of the decision tree, as recited by Applicant's amended independent claim 19.

Similarly, with respect to amended independent claim 37, Kroll fails to disclose or suggest a device comprising a processor programmed to select a first parameter configuration for a neurostimulator, receive an indication of observed efficacy of the first parameter configuration, select a branch of a decision tree based on the indication of observed efficacy and a position of the first parameter within the decision tree, wherein the decision tree defines a hierarchy of possible parameter configurations, and select a second parameter configuration for the neurostimulator based on the selected branch of the decision tree.

Application Number 10/767,545  
Amendment responsive to Final Office Action mailed July 30, 2007

For example, Kroll does not disclose or suggest selection of a branch of a decision tree based on the indication of observed efficacy and a position of the first parameter within the decision tree, and selection of a second parameter configuration based on the selected branch of the decision tree. Kroll also fails to disclose or suggest a decision tree defining a hierarchy of possible electrode configurations.

Instead, Kroll describes a device or user that positions or selects a lead or an electrode to deliver a pulse.<sup>1</sup> After the pulse is delivered, the user or device determines whether an optimal result was obtained.<sup>2</sup> If the result is not optimal, the device or user selects a new position or lead or electrode to deliver the next pulse.<sup>3</sup> Multiple positioning or selection iterations may be performed until an optimal and/or satisfactory result is produced.<sup>4</sup>

Kroll does not disclose or suggest that a branch of a decision tree is selected based on the indication of observed efficacy and a position of the first parameter configuration within the decision tree. Kroll merely teaches that the decision to continue testing new positions/electrodes is in response to a determination that the response was not optimal. In other words, even if Kroll could be considered to teach why and when a next position/electrode is selected, Kroll does not teach how the next position/electrode is selected. Such selection may be random or idiosyncratic.

In contrast, Applicant's claims require that a branch of a decision tree is selected based on the indication of observed efficacy of a tested first parameter configuration, and a position of the first parameter configuration within the decision tree. Applicant's specification, for example at paragraphs [0057] and [0058] and FIG. 5, describes traversing a branch extending from a previously tested node based on rating information for the previously tested node. The decision tree guides the processor to transition from the location of the first parameter configuration (e.g., node) within the decision tree to a second parameter configuration along a branch chosen based on the efficacy of the first parameter configuration.

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<sup>1</sup> Kroll, column 23, lines 1-2.

<sup>2</sup> Kroll, column 23, lines 13-14.

<sup>3</sup> Kroll, column 23, lines 15-17.

<sup>4</sup> Kroll, column 23, lines 15-20.

Application Number 10/767,545  
Amendment responsive to Final Office Action mailed July 30, 2007

Kroll does not teach how the next position/electrode is selected. Consequently, Kroll does not teach or suggest selecting a branch of a decision tree based on the indication of observed efficacy and a position of the first parameter configuration within the decision tree.

Furthermore, Kroll does not disclose or suggest the use of a decision tree to provide guidance in selecting an electrode configuration. Applicant has amended independent claims 19 and 37 to clarify that the decision tree defines a hierarchy of possible parameter configurations. Kroll does not describe how the position and/or selection of the lead and/or electrode is modified with each iteration, and does not disclose or suggest a decision tree hierarchy to aid in the positioning or selection. For at least these reasons, Kroll fails to disclose or suggest the requirements of independent claims 19 and 37.

***Claims 20-29, 32-36, 38-47, and 50-54***

Kroll fails to disclose or suggest each and every element set forth in independent claims 19 and 37. Claims 20-29 and 32-36 are dependent upon independent claim 19, and claims 39-47 and 50-54 are dependent upon independent claim 37. For at least the reasons described previously with respect to independent claims 19 and 37, Kroll fails to disclose or suggest the requirements of dependent claims 20-29, 32-36, 38-47, and 50-54.

Additionally, Applicant disagrees with the Office Action's finding that Applicant's claims contain intended use limitations. The Office Action stated, "Applicant's limitations of intended use such as lead placement and suggesting a configuration to the user are given no patentable weight since the leads and communication devices are not specified as part of the invention."<sup>5</sup> Applicant submits that, "[a] functional limitation must be evaluated and considered, just like any other limitation of the claim, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used."<sup>6</sup> Applicant submits that the claims clearly define the invention and requests consideration of all elements of Applicant's claims.

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<sup>5</sup> Office Action dated 2/2/07, page 2.

<sup>6</sup> MPEP 2173.05(g)

Application Number 10/767,545

Amendment responsive to Final Office Action mailed July 30, 2007

For example, Kroll fails to disclose or suggest a processor that selects first and second parameter configurations by suggesting the first and second parameter configurations to a user, as required by claims 32 and 50, or a processor that receives an indication relating to observed efficacy by receiving user input indicating observed efficacy, as required by claims 33 and 51. Claims 32, 33, 50, and 51 further limit the independent claims by defining functional limitations of the processor. Applicant requests consideration of these claim limitations in the subsequent Office Action.

Further, with respect to claims 23 and 41, Kroll fails to disclose or suggest leads implanted proximate to a spine of a patient. Kroll also fails to disclose or suggest a final electrode configuration that includes electrodes deployed on one more implanted spinal leads, as required by claims 28 and 46. Instead, Kroll describes positioning a lead in and/or near a patient's heart or near an autonomic nerve within a patient's body to affect cardiac function.<sup>7</sup>

Additionally, Kroll fails to disclose or suggest updating a decision tree based on observed efficacy, as required by claims 35 and 52. Kroll provides no teaching of hierarchical decision trees, and certainly does not suggest updating such a decision tree.

Further, with respect to claims 37 and 54, Kroll provides no teaching remotely suggestive of applying a first decision tree to determine a neurostimulation therapy type, neurostimulation device type, lead type and symptomatic indication, and applying a second decision tree based on the determination to select the second parameter configuration. The Office Action pointed to FIG. 8 as determining the type of stimulation. Even if the Office Action's interpretation of FIG. 8 of Kroll were correct, such a teaching would fall well short of what is recited in claims 37 and 54. These claims require determining a neurostimulation therapy type, neurostimulation device type, lead type and symptomatic indication. Moreover, the result of the method of FIG. 8 of Kroll is not application of a second decision tree based on a determination made by the method of FIG. 8.

Kroll fails to disclose each and every limitation set forth in claims 19-29, 32-47, and 50-54. For at least these reasons, the Office Action has failed to establish a prima facie case for anticipation of Applicant's claims 19-29, 32-47, and 50-54 under 35 U.S.C. § 102(b). Withdrawal of this rejection is requested.

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<sup>7</sup> Kroll, abstract and column 2, lines 47-62.

Application Number 10/767,545  
Amendment responsive to Final Office Action mailed July 30, 2007

**Claim Rejection Under 35 U.S.C. § 103(a)**

The Final Office Action rejected claims 30, 31, 48, and 49 under 35 U.S.C. § 103(a) as being unpatentable over Kroll. Applicant respectfully traverses the rejection. Kroll fails to disclose or suggest the inventions defined by Applicant's claims, and provides no teaching that would have suggested the desirability of modification to arrive at the claimed invention. Applicant submits that Kroll fails to disclose or suggest the requirements of claims 30, 31, 48, and 49 for at least the reasons stated previously with respect to independent claims 19 and 37. Claims 30 and 31 are dependent upon claim 19, and claims 48 and 49 are dependent upon claim 37. Dependent claims 30, 31, 48, and 49 are in condition for allowance for at least the reasons stated previously with respect to independent claims 19 and 37.

For at least these reasons, the Examiner has failed to establish a prima facie case for non-patentability of Applicant's claims 30, 31, 48, and 49 under 35 U.S.C. § 103(a). Withdrawal of this rejection is requested.

**CONCLUSION**

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims.

In view of the clear distinctions identified above between the current claims and the applied prior art, Applicant reserves further comment at this time regarding any other features of the independent or dependent claims. However, Applicant does not necessarily admit or acquiesce in any of the rejections or the Examiner's interpretations of the applied references. Applicant reserves the right to present additional arguments with respect to any of the independent or dependent claims.

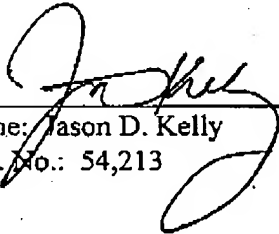
Application Number 10/767,545  
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Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

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